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DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

September 9, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John D. Valiante
CEO/Administrator
St. John's Hospital
P.O. Box 428
Jackson, Wyoming 83001

Ref. # - DEN-98-18

Dear Mr. Valiante:

During an inspection of your firm, Professional Home Care, 555 East Broadway, Jackson, WY, on July 16, 1998, Investigator Jill Mielziner determined that your firm transfills medical oxygen for home respiratory care. Medical oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that your product, Oxygen, U.S.P., is adulterated in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection include, but are not limited to the following:

1. Failure to test each lot of bulk liquid oxygen to determine conformance with appropriate specifications for identity and strength [21 CFR 211.84(d)(2)]. For example, each bulk shipment of liquid oxygen is accompanied by a certificate of analysis; however, a sample is not taken for identity testing directly from the commingled lot in the bulk storage tank or a sample is not taken for identity and strength testing from the first container filled from the commingled lot in the bulk storage tank after a new shipment has been added to the bulk tank.

2. Failure to test each [X] oxygen cylinder used in transfilling operations to determine conformance with appropriate specifications for identity and strength [21 CFR 211.84(d)(2)]. For example, no testing is performed on the [X] oxygen cylinders and a certificate of analysis is not received from the supplier.

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3. Failure to have standard operation procedures for:
   a. Performing prefill tests on oxygen cylinders [21 CFR 211.94(d)],
   b. Standardizing and calibrating the [redacted] oxygen analyzer [21 CFR 211.160(b)(4)], and
   c. Standardizing and calibrating thermometers [21 CFR 211.160(b)(4)].

4. Failure of batch production and control records to include the identification of the persons performing and directly supervising or checking each significant step in the filling of oxygen cylinders [21 CFR 211.188(b)(11)]. For example, a review of the Transfill Record From H Tanks to M6, C, D & E Tanks revealed a block for the signatures of the persons performing and the person checking the filling of oxygen cylinders, but their signatures were not always observed on the forms.

5. Failure to have all oxygen production and control records reviewed by the quality control unit to determine compliance with all established, approved written procedures before a batch is released and distributed [21 CFR 211.192]. For example, a review of the Transfill Record From H Tanks to M6, C, D & E Tanks revealed a block for the signatures of the persons reviewing all records related to a batch, but their signature was not always observed on the forms.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As Chief Executive Officer (CEO), it is your responsibility to assure adherence with all requirements of the Good Manufacturing Regulations.

At the conclusion of the inspection, Investigator Mielziner issued a written report of observations (FDA 483) to Tim D. Steinmetz, Respiratory DME Manager. As the CEO, you should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

Please advise this office, in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time; and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Mr. Russell W. Gripp, Compliance Officer, at the above address.

Sincerely,

Gary C. Dean
District Director

Enclosure:
As stated

cc: Becky Kimmel
Administrative Director
St. John's Hospital
P.O. Box 428
Jackson, Wyoming 83001

Tim D. Steinmetz
Respiratory DME Manager
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